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IN THE
Supreme Court of the United States

WARNER-LAMBERT COMPANY LLC
and PFIZER INC.,
Petitioners,

v.

KIMBERLY KENT, *et al.*,
Respondents.

On Writ of Certiorari to the
United States Court of Appeals for the Second Circuit

BRIEF OF AMICUS CURIAE AARP IN SUPPORT OF RESPONDENTS

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INTEREST OF AMICUS CURIAE[1]

AARP is a nonpartisan, nonprofit organization with nearly forty million members, including members in each of the fifty states and the District of Columbia. AARP works to foster the health and economic security of individuals as they age. To that end, AARP supports efforts at the state and national level to ensure access to safe and effective health products. AARP is greatly concerned about the safety of prescription drugs because older people disproportionately use them. AARP supports laws and public policies designed to protect its members' rights and to preserve the availability of legal redress when AARP members are harmed in the marketplace through no fault of their own.

AARP has a significant interest in this case. The issue before the Court directly affects the ability of AARP's members in Michigan to seek redress when injured by dangerous pharmaceutical products that were approved by the Food and Drug Administration (FDA), or remained on the market, notwithstanding the fact that the manufacturer intentionally violated FDA requirements.

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[1] Pursuant to Rule 37.6 of the Rules of the Supreme Court of the United States, no counsel for a party authored this brief in whole or in part, and no counsel or party made a monetary contribution intended to fund the preparation or submission of this brief. No person other than *amicus curiae*, its members, or its counsel made a monetary contribution to its preparation or submission. The parties have consented to the filing of this brief.

More broadly, the Court's resolution of the preemption question in this case may have repercussions in any case in which plaintiffs seek to make out common law tort or negligence *per se* claims by demonstrating that a drug's manufacturer intentionally violated federal statutory or regulatory requirements. Petitioners and their *amici* seek to forbid tort plaintiffs from relying on evidence that drug companies intentionally failed to submit required data, or deliberately misrepresented safety data, to the FDA. They contend that permitting plaintiffs to rely on such a showing might undermine FDA enforcement efforts.

History, of course, refutes that argument. State law tort claims founded on violations of federal law have been standard fare for decades, with no evidence of any impairment to the FDA. Limiting the right to recover for injuries caused by the intentional misconduct of drug companies, by barring plaintiffs from showing that their injuries resulted from the companies' deliberate failure to comply with federal standards, would deprive AARP members of the remedy historically guaranteed to them by common law. For these reasons, AARP has a strong interest in this case and it can offer a different perspective on the issues before the Court than those presented by the parties.

STATEMENT

1. Background

This case was dismissed by the district court on petitioners' Rule 12(c) motion for judgment on the pleadings. This statement is based on publicly available evidence that the plaintiffs would likely offer

to the trier of fact on remand. *See generally Desiano v. Warner-Lambert,* 326 F.3d 339, 341-43 (2d Cir. 2003); *In re Rezulin Prods. Liab. Litig.*, 210 F.R.D. 61, 63-64 & n.6 (S.D.N.Y. 2002). Rezulin is a prescription drug that was approved by the FDA in January 1997 for the treatment of Type-2 diabetes, and then marketed and sold by Warner-Lambert between March 1997 and March 2000. Rezulin's brief, three-year tenure on the market was marred by increasingly dire concerns over Rezulin's liver toxicity. Indeed, five times during those three years the FDA pushed Warner-Lambert to make significant modifications to Rezulin's label and prescribing information to require increasingly rigorous monitoring of patients' liver functions, reflecting the agency's growing concern about the dangers posed by the drug. *See id.; see also* Willman, *The Rise and Fall of the Killer Drug Rezulin*, L.A. TIMES, June 4, 2000, at A1 (hereinafter "Willman, *The Rise and Fall*").[2] Finally, in March 2000, at the FDA's request, Warner-Lambert withdrew Rezulin from the market. *See* Press Release, FDA, *Rezulin to Be Withdrawn from the Market* (March 21, 2000), *available at* http://www.fda.gov/bbs/topics/NEWS/NEW00721.html.

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[2] The FDA has only recently been given authority to mandate labeling changes. *See* Pub. L. 110-85, § 901 121 Stat. 823 (Sept. 27, 2007) (*to be codified at* 21 U.S.C. § 355(o)(4)). During the time Rezulin was on the market, the FDA had to negotiate with drug companies over the contents of labeling and drug warnings. *See* U.S. Gov't Accountability Office, *Drug Safety: Improvement Needed in FDA's Postmarket Decision-making and Oversight Process* 10 (2006) (GAO-06-402) (hereinafter "GAO Drug Safety Report").

There is also evidence suggesting that Warner-Lambert intentionally withheld information from, and misrepresented data to, the FDA in an effort to downplay evidence of Rezulin's liver toxicity. *In re Rezulin Prods. Liab. Litig.*, 210 F.R.D. at 63-64 & n.6 Warner-Lambert did so initially to obtain FDA approval for Rezulin and thereafter to keep Rezulin on the market. *See id.; see also* Whitcomb & Watkins, *Hepatic Dysfunction Associated with Troglitazone*, 338 New Eng. J. Med. 916 (1998). Warner-Lambert also resisted, for more than six months, the FDA's request that it cease marketing Rezulin as a stand-alone drug. *See* Willman, *"Fast-Track" Drug to Treat Diabetes Tied to 33 Deaths*, L.A. Times, Dec. 7. 1998, at 1. Throughout the three year period Rezulin was on the market, Warner-Lambert continually touted Rezulin's safety and denied the mounting evidence of its risks. *Desiano*, 326 F.3d at 342-43. Rezulin was responsible for ninety-four reported cases of liver failure, including sixty-six deaths.[3] Willman, *Hidden Risks, Legal Truths: Warner-Lambert Won Approval For Rezulin After Masking The Scope Of Liver Injuries In Clinical Studies*, L.A. TIMES, June 30, 2002, at 1.

2. Proceedings Below

The named plaintiff in this case, Kimberly Kent, is a resident of Michigan and the daughter of Virginia Kent, who died at age 62 from acute liver failure after

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[3] This figure is based on cases voluntarily reported to the FDA. Experts estimate that the actual number of liver failures and deaths may be as high as ten times this amount. Willman, *The Rise and Fall*; Nick Anderson, *Rezulin's Swift Approval, Slow Removal Raise Issues*, L.A. Times, March 23, 2000, at A1.

taking Rezulin. Individually, and as a class representative, Ms. Kent sued Warner-Lambert, alleging common law claims, including breach of implied and expressed warranties, negligence, negligent misrepresentation, negligence *per se*, fraud, defective design, defective manufacturing, and loss of consortium. *Kent* was filed in federal court in Michigan and was transferred by the Judicial Panel on Multidistrict Litigation to the United States District Court for the Southern District of New York. The District Court granted Warner-Lambert's motion for a judgment on the pleadings and dismissed the claims of Ms. Kent and other plaintiffs who had alleged that they or their loved ones sustained serious liver damage as a result of Rezulin.

The Second Circuit reversed. *Desiano v. Warner-Lambert*, 467 F.3d 85 (2d Cir. 2006). The court held that, under Michigan law, Ms. Kent's claims "depend primarily on traditional and preexisting tort sources, not at all on a 'fraud-on-the-FDA' cause of action created by state law, and only incidentally on evidence of such fraud." *Id.* at 98. The court decided that this distinguished the case from *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001). *Id.*

3. The Michigan Statute

Prior to 1995, Michigan law provided that, in a product liability action brought against a drug company, "compliance with governmental and industrial standards is admissible as evidence but is not [a] conclusive" defense. *Owens v. Allis-Chalmers Corp.*, 326 N.W.2d 372, 376 (Mich. 1982). In 1995, the Michigan legislature passed an amendment to the law

to provide a company a complete affirmative defense when, but only when, the company proves that both the drug and its labeling comply with FDA requirements. *Taylor v. Smithkline Beecham Corp.*, 658 N.W.2d 127, 134 (Mich. 2003).

The relevant section of the statute provides:

> In a product liability action against a manufacturer or seller, a product that is a drug is not defective or unreasonably dangerous, and the manufacturer or seller is not liable, if the drug was approved for safety and efficacy by the [FDA], and the drug and its labeling were in compliance with the [FDA's] approval at the time the drug left the control of the manufacturer or seller.

Mich. Comp. Laws § 600.2946(5). The statute further provides that, even if a company makes the threshold showing for a regulatory compliance defense, the defense is nonetheless forfeited if:

> [T]he defendant at any time before the event that allegedly caused the injury (a) [i]ntentionally withholds from or misrepresents to the [FDA] information concerning the drug that is required to be submitted under the food, drug, and cosmetic act . . . and the drug would not have been approved, or the [FDA] would have withdrawn approval for the drug if the information were accurately submitted. . . .[or] . . . (b) [it] [m]akes an illegal payment to an official or employee of the United States [FDA]

> for the purpose of securing or maintaining approval of the drug.

Id.

Petitioners contend that they have no affirmative duty to prove that Rezulin and its labeling were, in fact, in compliance with FDA requirements, beyond simply producing an FDA approval letter and submitting a declaration from a company official claiming that the company complied with applicable FDA requirements. Petitioners further claim that subsection (a), which denies companies a regulatory compliance defense if they have not been forthcoming with the FDA, is preempted and must be severed from the remainder of the statute because it requires proof of fraud on the FDA. As a result, petitioners ask this Court to rewrite Michigan law to provide them and other drug companies complete immunity from tort liability even if they intentionally disregard FDA requirements by withholding or misrepresenting health and safety data, even if the data would have been material to the FDA's approval, and, if one takes petitioners' argument to its logical conclusion, even if they make illegal payments to FDA officials.

4. The Federal Food, Drug, and Cosmetic Act

The Federal Food, Drug and Cosmetic Act (FDCA) requires companies seeking to obtain the FDA's approval to market a new drug to submit a "new drug application" containing all information bearing on the drug's safety and effectiveness, including the results of animal testing and pharmacological studies, as well as full reports of the clinical trials performed on human

subjects. 21 U.S.C. § 355(a)-(b); 21 C.F.R. Part 314. The FDA "determine[s] the kind and quantity of [additional] data an applicant must provide for a particular drug to meet the statutory standards." 21 C.F.R. § 314.105(c). The FDA may approve a new drug only if it determines that the drug is "safe and effective" for its intended uses and that its labeling is not "false or misleading." 21 U.S.C. §§ 321(p)(1)-(2), 355(b)-(d).[4]

Approval does not end a company's reporting obligations; on an ongoing basis, companies must provide the FDA with records "relating to clinical experience" and adverse reactions, file comprehensive annual reports, and permit the FDA to review their business records. 21 U.S.C. §§ 355(k), 374; 21 C.F.R. §§ 314.80, 314.81. It is unlawful to withhold or intentionally misrepresent health and safety information submitted to the FDA. *See, e.g.*, 18 U.S.C. § 1001; 21 U.S.C. §§ 307b(a)(1), (a)(4); 355(b), (k). And the FDCA is quite clear that the Secretary "shall" deny or withdraw approval of a drug if "the application contains any untrue statement of material fact." 21 U.S.C. § 355(e)(5); *see also id.* § 355(j)(3)(K).

INTRODUCTION AND SUMMARY OF ARGUMENT

AARP files this brief as *amicus curiae* to make three points that may not stand out in respondents' more comprehensive treatment of the issues:

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[4] *See also* http://www.fda.gov/cder/regulatory/applications/default.htm (describing the drug approval process).

First, the claims of Ms. Kent and the other respondents are garden-variety common law tort claims that have been raised against drug companies for decades. *See generally Merrell Dow Pharm. Inc. v. Thompson*, 478 U.S. 804 (1986); *see also* David A. Kessler & David C. Vladeck, *A Critical Examination of the FDA's Efforts to Preempt Failure-to-Warn Claims*, 96 Geo. L.J. 461 (2008). At no point has this or any other appellate court held that federal law preempts traditional common law claims involving FDA-approved drugs.[5] Given the absence of an express preemption provision in the FDCA, and Congress' longstanding awareness of products liability litigation against drug companies, this is unsurprising. *See Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 161-67 (1989). The fact that Michigan provides a regulatory compliance defense that is stronger than most other states' does not change the nature of the plaintiffs' claim in this case. For this reason, the Court's ruling in *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001), setting aside a novel "fraud-on-the-FDA" claim on conflict preemption grounds, has no bearing here.

Second, to shoehorn this case into *Buckman*'s mold, petitioners and their *amici* rewrite Michigan law to reverse both the order and the burden of proof established by the Michigan statute. The point of the

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[5] The Court has been asked to grant review in *Wyeth v. Levine*, *petition for cert. pending*, No. 06-1249 (filed Mar. 12, 2007), to decide whether state tort failure-to-warn claims are preempted by virtue of FDA-approved labeling, where the drug company can show that its drug was labeled in compliance with FDA standards.

Michigan law is to give companies that play by the rules the benefit of a complete regulatory compliance defense that is generally unavailable under common law. But the statute does not seek to extend liability protection to companies that play fast and loose with FDA requirements. For that reason, the statute requires a company claiming a regulatory compliance defense to show that it "*properly* obtained FDA approval." *Taylor*, 658 N.W.2d at 134 (emphasis added). The statute places the initial burden on the company to *prove*, not simply allege, that the drug and its label in fact "*were in compliance with*" FDA approval requirements when the drug left the company's hands. Mich. Comp. Laws § 600.2946(5) (emphasis added). Companies that intentionally withhold or deliberately misrepresent vital safety information required by the FDA cannot establish compliance with FDA requirements, *see* 21 U.S.C. §§ 307b(a)(1), (a)(4), 355(b), (e)(5), (j)(3)(K), (k), and therefore cannot make the threshold showing required by Michigan law.

To be sure, the Michigan statute goes on to provide that, even if a company satisfies the threshold requirement of showing regulatory compliance, the defense is nonetheless unavailable if the company intentionally withholds or misrepresents data to the FDA and the drug would not have been approved, or the FDA would have withdrawn approval, if accurate information were submitted. Mich. Comp. Laws § 600.2946(5)(a). In other words, the defense is unavailable if the company makes a material misrepresentation to, or withholds material information from, the FDA. That approach appears to mirror the one established in the FDCA, which authorizes civil

penalties for such conduct and directs the FDA to deny or withdraw its approval of a drug where the sponsor has made an "untrue statement of material fact." *See* 21 U.S.C. § 355(e)(5); *see also id.* § 355(j)(3)(K). As explained below, subsection (a) is not preempted under *Buckman* because courts can determine a company's liability without the FDA's participation and because a determination that a company violated subsection (a) would not implicate, let alone interfere with, the FDA's enforcement or regulatory prerogatives.

Third, if the Court disagrees and finds subsection (a) preempted, then it must remand this case for resolution of the thorny severability question that such a ruling would pose. Given the clear goal of the Michigan legislature to provide broader but not unlimited liability protection to drug companies, simply severing subsection (a) of Mich. Comp. Laws § 600.2946(5) from the remainder of the statute would turn the Michigan law on its head. Such a ruling would confer blanket immunity on a drug company even though it intentionally withheld or distorted material information to the FDA, even though truthful information would have led the FDA to withdraw the drug's approval, and presumably even if the company made illegal payments to FDA officials. Such a result cannot be squared with the evident purpose of the Michigan legislature to give liability protection only to those companies that "properly obtained FDA approval." *Taylor*, 658 N.W.2d at 134. Therefore, if this Court holds that any portion of Mich. Comp. Law § 600.2956(5)(a) is preempted, the case should be remanded to the Second Circuit with directions to undertake further proceedings to address severability.

ARGUMENT

I. *Buckman* Does Not Preempt The Traditional Common Law Claims At Issue Here.

In *Buckman*, this Court addressed a narrow legal question based on an unusual set of circumstances. The defendant, Buckman, was a consultant hired by AcroMed to help it obtain FDA approval for orthopedic bone screws. *Buckman*, 531 U.S. at 343. The plaintiffs were individuals claiming injuries caused by the bone screws. *Id.* They successfully asserted state tort claims against AcroMed. However, the plaintiffs had no traditional theory of liability against Buckman because, as a consultant, Buckman had no contact with patients or doctors and was not involved in the manufacture or sale of the screws.

Undeterred, the plaintiffs advanced a novel "fraud-on-the-FDA claim," which premised liability on the theory that Buckman had defrauded the FDA. The Court rejected this theory, holding that such claims "conflict with, and are therefore impliedly preempted by," the FDCA. *Id.* at 347. The Court observed that the plaintiffs' claim did not "rely[] on traditional state tort law which had predated the federal enactments in question," that their "claim[] exist[ed] solely by virtue of the FDCA disclosure requirements," and that "the existence of these federal enactments [was] a critical element in their case." *Id.* at 353.

In contrast, the claims at issue here—common law tort claims—are premised on traditional tort duties product manufacturers owe to Michigan consumers. *See Desiano*, 467 F.3d at 88, 94-95. None of the claims

rely on the existence of FDCA disclosure requirements or other federal laws. And nothing in *Buckman* suggests that traditional common law claims are preempted. To the contrary, the *Buckman* Court found that the ordinary presumption against preemption did not apply in that case because the claim for relief at issue did not arise under common law, but in fact derived from the FDCA itself. *Buckman*, 531 U.S. at 347. The Court ruled that policing fraud against the FDA was a job for the FDA to handle. *Id.* at 348. But that logic has no bearing in this case, which concerns the common law duties that drug companies owe consumers. The job of compensating people injured through the fault of others has historically been the exclusive province of state tort law. The *Kent* respondents have invoked common law claims to remedy wrongdoing by Warner-Lambert against themselves and their loved ones who were killed or seriously injured by Rezulin. Because these claim arise under conventional state tort law, *Buckman* is not controlling. *See id.*; *see also Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996) (invoking presumption against preemption to preserve common law claims).

II. Subsection (a) Is Not Preempted.

Petitioners concentrate their fire on subsection (a) of Mich. Comp. Laws § 600.2946(5), as if it is the keystone of the statute. But that reading of Michigan law is plainly wrong. The statute begins by offering drug companies expanded protection from tort liability where the company can show that it dutifully complied with FDA requirements. As the Michigan Supreme Court has observed, "the [Michigan] Legislature has determined that a drug manufacturer or seller that has

properly obtained FDA approval of a drug product has acted sufficiently prudently so that no tort liability may lie." *Taylor*, 658 N.W.2d at 134 (emphasis added).

Thus, to make out a regulatory compliance defense under Michigan law, the initial burden falls on Warner-Lambert to prove not just that it obtained FDA approval, but that it *"properly"* obtained FDA approval and sold Rezulin "in compliance with FDA approval" requirements. *Id.* (emphasis added); Mich. Comp. Laws § 600.2946(5). The statute therefore requires something more from a drug company than simply producing an FDA approval letter and a self-serving declaration from a company official asserting that the company has fully complied with FDA requirements. The statute, in the words of *Taylor*, requires the company to show that it has "properly" obtained FDA approval. To make that showing, the company would be required either to demonstrate that it did not withhold or distort information that may have been material to the FDA's approval decision, or, at the very least, to refute plaintiffs' evidence that the company engaged in wrongdoing. Indeed, that is the ordinary allocation of the burden of proof in cases in which drug companies seek to take advantage of a regulatory compliance defense. *See* Robert L. Rabin, *Reassessing Regulatory Compliance*, 88 Geo. L.J. 2049 (2000).

Under this conventional reading of Michigan law, evidence that Warner-Lambert intentionally withheld or misrepresented required information is relevant to, and would refute, Warner-Lambert's claim of compliance. *See, e.g.*, 21 U.S.C. § 355(b), (e)(5), (j)(3)(K), (k). For this reason, the linchpin of the statute is the burden it places on drug companies to establish all of

the elements of a traditional regulatory compliance defense; only if a company does so is it eligible for the complete defense offered by Michigan law. Petitioners and their *amici* would have the Court simply skip over this crucial step of the analysis, but this step is plainly compelled by Michigan law.[6]

Petitioners ask the Court to bypass the threshold test under Michigan law and go immediately to the second step in the statute, which functions as a failsafe. This part of the statute disqualifies a company for a regulatory compliance defense if the company (a) withheld information from, or misrepresented information to, the FDA that was material to the FDA's approval process, or (b) made illegal payments to FDA officials. Mich. Comp. Laws § 600.2946(5)(a)&(b).[7] Petitioners claim that sub-

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[6] This reading of the statute, which is compelled by *Taylor*, suggests that consideration of the issue presented in this case is premature. Given the district court's dismissal of the case on Rule 12(c) grounds, and the Second Circuit's reversal of that ruling, there has been no opportunity for the plaintiffs to develop facts relevant to whether Warner-Lambert intentionally withheld records from the FDA that it was required to submit or misrepresented facts to the agency. If there is evidence that Warner-Lambert used improper means to obtain FDA approval, or to keep Rezulin on the market, then the company's effort to take advantage of Michigan's complete regulatory compliance defense would fail at the threshold, *see Taylor*, 658 N.W.2d at 134, and the preemption question presented in this case would not arise. For that reason, the Court might want to consider whether the writ was improvidently granted or whether the case should be remanded for a more thorough evaluation of this threshold question under a proper reading of Michigan law.

[7] While petitioners' reluctance to address subsection (b) (continued...)

section (a) amounts to a requirement that the plaintiff prove "fraud-on-the-FDA" to make out their common law claims, and thus their claims are preempted under *Buckman*.

This argument is flawed. *Buckman*'s core holding is that the FDA must be given breathing room to take measures to safeguard itself against fraud. Judicial intervention might interfere with that interest. But subsection (a) does not implicate that concern. Enforcement of subsection (a) neither requires the FDA's participation nor interferes with FDA enforcement or regulatory prerogatives.

Nothing in the Michigan statute calls on courts to second-guess FDA regulatory or enforcement decisions. There is a long history of products liability litigation against the drug industry based on claims that a company made misrepresentations to or withheld material information from the FDA.[8] That litigation

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[7](...continued)
may be understandable, the provision cannot simply be ignored. Under the logic of petitioners' argument, a claim under subsection (b) would be preempted as well, since the FDA can be expected to police instances of bribery as vigorously as instances of fraud. But such a conclusion would require the wholesale revision of Michigan law, which plainly sought to deny liability protection to companies that bribe FDA officials.

[8] *See, e.g., Stanton v. Astra Pharmaceutical Products, Inc.*, 718 F.2d 553, 559-62 (3d Cir. 1983) (failure to submit adverse reaction reports); *Ezagui v. Dow Chem. Corp.*, 598 F.2d 727, 733 (2d Cir. 1979) (failure to adequately warn of drug's risk); *Hoffman v. Sterling Drug, Inc.*, 485 F.2d 132, 138 (3d Cir. 1973) (failure to seek FDA approval for new use of drug); *Toole v. Richardson-*
(continued...)

has proceeded in both federal and state courts for decades with no claim that it has interfered with the FDA's ability to enforce the law. There is no reason why now, all of a sudden, that litigation threatens the FDA's ability to do its job.

The structure of the Michigan statute serves as a safeguard against interference with the FDA. The statute places the initial burden on the company to prove its regulatory compliance defense. The evidence needed to substantiate the company's claim would come from the company's own files—not from the FDA. And in cases like this one, where the heart of the plaintiffs' claim is that the petitioners withheld information from and misrepresented data to the FDA, those facts are objective ones that can be established, as they are every day in ordinary tort litigation, on the bases of the company's records and expert evaluation of them, without the FDA's involvement.[9] *See supra* note 8.

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[8](...continued)
Merrell, Inc., 60 Cal. Rptr. 398 (Cal. App. 1967) (submission of false and misleading information to the FDA); *Orthopedic Equip. Co. v. Eutsler*, 276 F.2d 455, 461 (4th Cir. 1960) (sale of misbranded medical device); *see also Bristol-Myers v. Gonzales*, 561 S.W.2d 801 (Tex. 1978) (failure to adequately warn of drug's risk, where company knew of risk before it alerted the FDA); *Stevens v. Parke, Davis & Co.*, 507 P.2d 653 (Cal. 1973) (failure to adequately warn of drug's risk); *Parke-Davis and Co. v. Stromsodt*, 411 F.2d 1390, 1402 (8th Cir. 1969) (failure to adequately warn of drug's risk and inadequate testing of drug).

[9] The FDA has long and generally successfully resisted efforts by parties to private litigation to force the agency to participate. *See* 21 C.F.R. § 20.1; *see also In re David A. Kessler*, 100 F.3d 1015, 1016 (D.C. Cir. 1996).

Nor is there force to petitioners' argument that litigating over a subsection (a) claim would somehow enmesh the FDA in private tort litigation. Petitioners argue that the language in subsection (a) requires a showing that the FDA found fraud or would have denied or withdrawn approval if the information had been accurately submitted. But that overstates the burden imposed by the Michigan statute, which does not use the word fraud. In fact, the language of the Michigan statute, as a practical matter, mirrors federal law. Under the FDCA, the FDA "shall" deny or withdraw approval of a drug if "the application contains any untrue statement of material fact" 21 U.S.C. § 355(e)(5); *see also* § 355(j)(3)(K). Under Michigan law, courts shall deny companies a regulatory compliance defense if they have omitted or distorted information that would affect an FDA approval decision. Thus, the question under Michigan law distills to whether the company's omission or distortion of information was "material." Questions of materiality are generally the province of courts, and courts routinely make materiality decisions notwithstanding the fact that they may also be made by agencies that have concurrent enforcement authority.[10] There is no reason why Michigan courts,

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[10] *See, e.g., Merrill Lynch, Pierce, Fenner & Smith Inc. v. Dabit*, 547 U.S. 71 (2006) (determination of materiality in securities case made by courts, not just the Securities and Exchange Commission); *Burlington Northern & Santa Fe Ry. v. White*, 126 S. Ct. 2405 (2006) (determination of materiality of adverse employment action taken allegedly in retaliation for exercising protected rights made by courts and not just the Equal Employment Opportunity Commission); *see also Neder v. United States*, 527 U.S. 1 (1999) (question of materiality for the courts

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or federal courts applying Michigan law, cannot reach decisions about materiality without the FDA's involvement.

It also bears emphasis that courts will need to reach the questions posed by Mich. Comp. Laws § 600.2946(5)(a), (b) only in the rarest cases. As noted above, the statute places an initial, affirmative duty on the company to prove all elements of regulatory compliance, and evidence of material information withheld, or material information misrepresented, would negate such a defense. Subsections (a) and (b) deny a defense to companies that might satisfy the basic requirements for the regulatory compliance defense but have nonetheless engaged in serious and disqualifying misconduct. But the inquiry called for under subsection (a) is no different than the inquiry courts will have to make in assessing the evidence produced to support or rebut the company's regulatory compliance defense: just as material omissions and misstatements would refute a company's claim to a regulatory compliance defense, so too would they disqualify a company under subsection (a). There is no reason why evidence the company could use *to establish* the regulatory compliance defense it seeks under Mich. Comp. Laws § 600.2946(5) is somehow tainted if used by the plaintiff *to disqualify* the company from the defense under subsection (a). Petitioners offer no explanation as to why their use of

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[10](...continued)
under tax fraud statute); *see also* Fed. R. Civ. P. 56 (courts determine whether a fact in genuine dispute is "material" in deciding summary judgment motions). *See generally KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727 (2007)).

evidence to support a regulatory compliance defense raises no preemption concerns while respondents' use of similar evidence to rebut the company's defense is preempted.

There are two additional concerns raised by the *Buckman* Court that further undercut petitioners' claims. First, the *Buckman* Court worried that expanding liability by permitting novel claims like the fraud-on-the-FDA claim asserted by the *Buckman* plaintiffs might discourage the development of beneficial, but potentially risky, new products. *Buckman*, 531 U.S. at 350-51. This concern has no force here. The Michigan statute *limits* traditional common law liability; it does not create a new cause of action or expand liability under an existing cause of action. *See Taylor*, 658 N.W.2d at 131; *see also Desiano*, 467 F.3d at 94-95.

Second, the *Buckman* Court was concerned that expanding potential tort liability might create an "incentive for drug companies to submit a deluge of information that the [FDA] neither wants nor needs." *Id.* at 351. At least with the FDA's regulation of drugs, in contrast to the regulation of medical devices involved in *Buckman*, this concern is misplaced. It is hard to imagine what information a drug company might have that even tangentially relates to the safety of the drug that the company is not already required to submit to the FDA. *See* 21 C.F.R. § 314.50.[11]

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[11] FDA regulations are comprehensive, leaving no room for an applicant to omit information that might be relevant to the drug's approval. Among other things, the FDA requires a

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Finally, petitioners' reading of subsection (a) of the Michigan statute as requiring a formal FDA finding of fraud or decision to withdraw approval for a drug on the basis of safety concerns would render the provision a dead letter. Neither petitioners nor their *amici* (including the United States) can cite a single instance in which the FDA took either measure. Nor can they point to an example where the FDA, once it took enforcement action, went on to declare what impact, if any, the misconduct had on its approval determination.

Petitioners' silence is unsurprising. The GAO reports that, "[s]ince 2000 there have been 10 drug withdrawals for safety reasons, and in all of these cases the drug's sponsor voluntarily removed the drug from the market." GAO Safety Report, *supra* note 2, at 10. The GAO goes on to note that the "FDA does not have explicit authority to require that drug sponsors take other safety actions," but when the FDA identifies a problem, "sponsors generally negotiate with the FDA to avoid other regulatory action." *Id.* And the FDA's own Science Advisory Board reports that the FDA has all but stopped bringing enforcement cases against manufacturers of approved drugs.[12] Thus, to find that

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[11](...continued)
company to submit, as a precondition to approval, an "integrated summary of *all* available information about the safety of a drug product . . .." 21 C.F.R. § 314.50(d)(5)(vi)(a) (emphasis added); *see also* § 314.80 (spelling out comprehensive reporting requirements for drugs post-approval).

[12] FDA Science Board, *Report of the Subcommittee on Science and Technology, FDA Science and Mission at Risk* (Nov. 2007), *available at* http://www.fda.gov/ohrms/dockets/ac/07/briefing/2007-4329b_02_00_index.html. The decline in enforce-
(continued...)

the Michigan legislature intended subsection (a) to require formal FDA action would be to ascribe a singularly irrational intent on its part: namely, that it made a statutory trigger contingent on FDA action the agency rarely, if ever, takes.

III. The Court Should Remand The Severability Question.

The ruling below is correct and should be affirmed. If this Court disagrees, the case must be remanded for consideration of the severability question—that is, whether subsection (a) of Mich. Comp. Laws § 600.2946(5) is severable from the remainder of the statute, or whether the statute is invalid in its entirety. In AARP's view, there is a serious federalism problem that runs through this case. The statute at issue is a Michigan statute, yet because of the routine removal of cases to federal court, it has not yet been authoritatively construed by a Michigan court, apart from the Michigan Supreme Court's ruling in *Taylor* upholding the statute in the face of a challenge to its constitutionality under the Michigan Constitution.

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[12](...continued)
ment activities by the FDA is nothing short of stunning. In 1991, 1992, and 1993, the agency brought 468 civil seizure actions, 75 criminal injunction cases, and 121 criminal prosecutions; in 2004, 2005, 2006, and 2007, the agency bought just 53 civil seizure actions, 57 criminal injunction cases, and *zero* criminal prosecutions. *FDA Science and Mission at Risk*, at Appendix B-22 - B-23. Tellingly, the *only* FDA enforcement case petitioners or the United States cites, *United States v. Lane Labs*, 427 F.3d 219 (3d Cir. 2005), was *not* an action to withdraw approval of an approved drug. It was instead an action for injunctive and equitable relief against the sellers of *unapproved* drugs, namely shark cartilage and other products as cures for cancer and HIV infection.

We urge this Court to reject Warner-Lambert's argument that this Court should make the severability determination on its own and sever just subsection (a) from the remainder of Mich. Comp. Laws § 600.2946(5). For one thing, the severability issue is not subsumed within the question presented in this case and therefore is not before the Court. For another, such a Procrustean approach to severability would do violence to the Michigan statute's goal, which is to provide drug companies that play by the FDA's rules a complete regulatory defense, but to withdraw that defense when companies engage in conduct that taints the approval process. Severing just the portion of the statute Warner-Lambert urges would turn a strong-but-conditional defense into a blanket immunity and would give protection to drug companies far beyond that intended by the Michigan legislature. For this reason, in the event that the Court disagrees with the Second Circuit, we urge the Court to remand this case for reconsideration of the severability question.

CONCLUSION

For the reasons set forth above and in respondents' brief, the judgment below should be affirmed.

Respectfully submitted,

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